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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,657	05/25/2000	Misako Mizuno	029430-454	6902

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/21/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/577,657

Applicant(s)

MIZUNO ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 29-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 29-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 27.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Claims 1-28 have been cancelled and claims 29-53 have been added, as requested in Paper No. 28, filed 6 March 2003.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. A substitute specification is required for the reasons specified in the Office action mailed 16 October 2001.

### ***Claim Objections***

4. Claims 31, 36 and 51 are objected to because of the following informalities:  
  
Claims 31 and 36 start with an improper article.  
  
In claim 51, line 2, "are" should be --is-- and articles are missing before both recitations of "cultured".
5. Claim 51 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Parent claim 49 already specifies that the plant is Camellia or Coffee.

### ***Claim Rejections - 35 USC § 112***

6. Claims 29-32, 34-37, 39-49 and 52-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO:2 and plant cells

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and plants transformed with those nucleic acids, does not reasonably provide enablement for nucleic acids that encode SEQ ID NO:1, encode modified nucleic acids or that hybridize under unspecified stringency to nucleic acids that encode SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 6 December 2002, as applied to claims 1-2, 4-5, 7, 13-14, 16-17, 20-21, 23 and 27-28. Applicant's arguments filed 6 March 2003 have been fully considered but they are not persuasive.

Applicant urges that it is within the ability of one of skill in the art to use the teachings of the specification to modify nucleotide sequences and determine if the sequences maintain the desired enzymatic activity [*sic*] or if they hybridize to SEQ ID NO:1 [*sic*]. Applicant asserts it is routine to develop a nucleic acid that encodes SEQ ID NO:1 and points to examples 4-7 for use of RT-PCR to isolate the coding sequence from a tea cDNA library (response pg 9-11).

This is not found persuasive. The specification does not teach the primers for use in RT-PCR in isolating the claimed nucleic acid from other plant species. Additionally, the exact hybridization or amplification conditions to use in isolation of nucleic acids other than SEQ ID NOs:2-3 are not provided. The specification does not teach the amino acid motifs critical for enzymatic function, and thus provides no guidance for making the claimed nucleic acids. Making and analyzing more than  $19^{356}$  nucleic acids would require undue experimentation, as discussed in the prior Office action. The making portion of this enablement rejection is not directed to how to make nucleic acids encoding SEQ ID NO:1.

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Applicant urges that a nucleic acid encoding only SEQ ID NO:1 would encode an enzyme with the listed properties because Table 1 and examples 1-2 and 9 show that such a nucleic acid does, even though the starting ATG is missing. Applicant also cites Kato et al, which teaches that a purified caffeine synthase has a modified N-terminus; thus, truncated proteins are functional (response pg 11).

This is not found persuasive. The rejection is not that the protein with a modified N-terminus is not functional, but that a nucleic acid encoding such a protein cannot be expressed in a cell because it lacks a starting ATG. In example 9, *E. coli* was transformed with a nucleic acid of SEQ ID NO:2, which encodes a protein that has a 13 amino acid N-terminal extension compared to SEQ ID NO:1. Examples 1 and 2 and Table 1 only teach the isolation of the enzyme, and thus do not teach expression of a nucleic acid encoding only SEQ ID NO:1 in a cell. Applicant is again invited to provide a Declaration showing data in which *E. coli* transformed with a nucleic acid that only encodes SEQ ID NO:1, *i.e.*, that has no starting ATG, produces an enzyme with the listed properties.

Applicant urges that it is within the purview of one of skill in the art and the teachings of the specification to make and use anti-sense suppression genes that are not completely homologous to the target gene to inhibit sense gene transcription. Applicant urges that the specification on pg 25 teaches making and using antisense DNA and urges that example 10 teaches antisense suppression of the N-methyl transferase gene in a caffeine producing plant (response pg 11-13).

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The rejection was made because the instant specification provides no guidance for altering the "composition" of caffeine; amendment of the claims to change "composition" to "concentration obviates this portion of the rejection.

7. Claims 30, 32, 35, 37, 40, 42, 44, 46, 48 and 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 6 December 2002, as applied to claims 1-2, 4-5, 7, 13-14, 16-17, 20-21, 23 and 27-28. Applicant's arguments filed 6 March 2003 have been fully considered but they are not persuasive.

Applicant urges that in *In re Bell*, it was stated that in molecular biology disclosure of the amino acid sequence provides an explicit disclosure of the nucleic acid sequence. Applicant urges that therefore is it within the purview of one of skill in the arts to modify nucleotide sequences and determine if the sequences maintain the desired enzymatic activity [*sic*] or if they hybridize to SEQ ID NO:1 [*sic*] (response pg 13-15).

This is not found persuasive. The rejection is not made against claims directed to nucleic acid encoding SEQ ID NO:1 but to nucleic acid that hybridize to nucleic acid encoding SEQ ID NO:1. The specification does not teach the structural features, *i.e.*, the sequence, of nucleic acids that hybridize to a nucleic acid that encodes SEQ ID NO:1 and that encode a protein with N3-methyl transferase, theobromine N1 methyl transferase and paraxanthine N3 methyl transferase activities. The critical structural motifs that distinguish nucleic acids that encode functional enzymes from those that do not are not described.

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8. Claims 30-33, 35-38, 40, 42, 44, 46, 48, 51 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 6 December 2002, as applied to claims 1-7, 13-14, 16-17, 20-21, 23 and 27-28. Applicant's arguments filed 6 March 2003 have been fully considered but they are not persuasive.

Applicant urges that the new claims render these rejections moot (response pg 15-16).

This is not found persuasive because the following rejections are new, due to amendment:

Claim 30 lacks antecedent basis for the limitation "the nucleotide sequence of claim 29" as claim 29 is drawn to a DNA molecule.

Claims 30 and 35 lack antecedent basis for the limitations "the resultant solution" in line 10 and "the probe" in line 19.

Claims 30 and 35 are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. This particularly true of parts (iii) and (v).

In claims 30 and 35, part iii, is the probe only labeled at the recited temperature? Being labeled by a label is repetitious. The claims lack antecedent basis for "the hybridization" in line 17. With respect to the recitation of "several hours necessary for the hybridization" - is one supposed to determine if several hours are necessary for the hybridization? What if less time is required?

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In claims 30 and 35, part v, is the purpose to identify the probe or the claimed nucleic acid? How does identifying the probe relate to the claimed nucleic acid?

Claims 30 and 35, part iv, are indefinite in their recitation of the washing conditions because no times, temperatures or salt concentrations are recited. As these conditions are necessary to define the metes and bounds of the claimed nucleic acid, the claim is indefinite.

Claim 35 lacks antecedent basis for the limitation "the nucleotide sequence of claim 34" as claim 34 is drawn to an RNA molecule.

Claim 51 lacks antecedent basis for the limitation "said transformed whole plant" in lines 1-2.

9. Claims 29-53 are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid encoding SEQ ID NO:1 or encoding a N-methyl transferase with 7-methylxanthine N3 methyl transferase, theobromine N1 methyl transferase and paraxanthine N3 methyl transferase activities.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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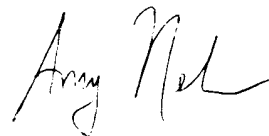
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.

May 5, 2003

A handwritten signature in cursive script, appearing to read "Amy Nelson".

**AMY J. NELSON, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**